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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/086,913	03/01/2002	Maria De Lourdes Higuchi	A33474-PCT-USA-A - 068528	1698
21003	7590	10/05/2004	EXAMINER MONSHIPOURI, MARYAM	
BAKER & BOTTS 30 ROCKEFELLER PLAZA NEW YORK, NY 10112			ART UNIT 1652	PAPER NUMBER

DATE MAILED: 10/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Supplementary
Office Action Summary

Application No.

10/086,913

Applicant(s)

HIGUCHI ET AL.

Examiner

Maryam Monshipouri

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-15 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input checked="" type="checkbox"/> Other: <u>attachment</u> |

Applicant's response to restriction requirement filed 7/19/2004 is acknowledged. Applicant elected Group I invention directed to claims 1-9 without traverse. However, upon further review of currently pending claims and lack of unity letter (case # PCT/BR01/00083) which was mailed to Brazil on March 27, 2002 the examiner ran into **confusion as to what the exact subject matter of claims is/are**. In an effort to clarify this confusion the examiner on 9/24/2004 attempted to call the attorney of applicant namely, Ms. Lisa B. Kole at the telephone no. (212)408-2568. However, Ms. Kole could not be reached at said telephone number. The examiner then used the telephone number of applicant's according to PALM (USPTO internal) records, namely, (212) 705-5000 but was again unsuccessful in reaching Ms. Kole.

Therefore, in view of **examiner's confusion** a new restriction letter is issued as follows:

Group I, claims 1-5, 7-10, drawn to neuraminidase enzyme and compositions comprising said enzyme, classified in class 435, subclass 200.

Group II, claims 1-10, drawn to trans-salivate enzymes and compositions comprising said enzyme, classified in class 435, subclass 201.

Group III, claims 1-10, drawn to trans-sialidase/neuraminidase enzymes and compositions comprising said combination of enzyme, classified in class 435, subclass 189.

Group IV, claims 11-15, drawn to methods of treating cell proliferation using said trans-sialidase compositions, classified in class, 424, subclass 94.61.

The inventions are patentably each from the other because of the following reasons:

Inventions of Groups I-III are patentably distinct each from the other because each product has an unrelated chemical structure and function.

Inventions II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the enzymes of Group I may be used for antibody preparation which is totally different method than that of Group IV.

Inventions of Groups I and III are each unrelated to the methods of group IV because said products alone are neither used nor made by said method.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or other wise

include all the limitations of the allowable product claim will be rejoined in accordance with the provision of MPEP section 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all the criteria for patentability including the requirement of 35 U.S.C. 101, 102, 103 and 112. Until an asserted product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. section 103(b)," 1184 O.G. 86(March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include limitations of the product claim. **Failure to do so may result in a loss of the right to rejoinder.**

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Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP section 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant is requested to firstly provide the Office with a proper telephone number he/she may be reached. Secondly, in order to expedite prosecution, applicant is requested to amend at least the elected claims such that the claimed subject matter can be clearly understood. A copy of lack of unity letter sent to Brazil is enclosed for applicant's attention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maryam Monshipouri whose telephone number is (571) 272-0932. The examiner can normally be reached on 7:00 a.m to 4:30 p.m. except for alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnanthapu Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

M. Monshipouri

Maryam Monshipouri Ph.D.

Primary Examiner

BOX II. OBSERVATIONS WHERE UNITY OF INVENTION WAS LACKING

This ISA found multiple inventions as follows:

This application contains the following inventions or groups of inventions which are not so linked as to form a single inventive concept under PCT Rule 13.1.

Group I, claim(s) 1-8, 11-15, drawn to an enzyme having activities from the group consisting of :trans-sialidase, neuraminidase and a combination thereof, compositions comprising said enzyme for treatment of increased cell proliferation, methods of treating cell proliferation using said composition.

Group II, claim(s) 1-10, drawn to said enzyme, compositions comprising said enzyme for the treatment of a disorder characterized by coinfection with mycoplasma and a second microbe.

the special technical feature of Group I invention is treating a disorder characterized by increased cell proliferation which is distinct from an enzyme having neuraminidase and trans-sialidase activity or combination thereof and a composition comprising said enzyme for treating a disorder characterized by coinfection with mycoplasma and a second microbe, which is the special technical feature of Group II invention. Further, cell proliferation disorder could occur independently of infection with mycoplasma and a second microbe disorder.